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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,636	05/24/2001	Hatim Allawi	FORS-04944	3371

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MEDLEN & CARROLL, LLP  
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SUITE 350  
SAN FRANCISCO, CA 94105

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/864,636

Applicant(s)

ALLAWI ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33,36 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33,36 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicant's election without traverse of Group 1, claims 1-45 in the reply filed on 6/25/04 is acknowledged. Claims reciting the 144 other different sequences have been cancelled in addition to claims drawn to the other groups. Therefore all of the pending claims, i.e. 1-33, 36 and 41-45, will be examined. Election was made **without** traverse in the reply filed on 6/25/04.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33, 36 and 41-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 5,846,717, claims 1-20 of U.S. Patent No. 5,985,557, claims 1-34 of U.S. Patent No. 5,994,069, claims 1-15 of U.S. Patent No. 6,001,567, claims 1-27 of U.S. Patent No. 6,090,543, claims 1-72 of U.S. Patent No. 6,348,314 and claims 1-27 of U.S. Patent No. 6,458,535. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are essentially a rewording of the same method. The claims of all of the instant patents except for 6,458,535 are drawn to methods for detecting the presence of a target nucleic acid molecule by detecting non-target cleavage products while the claims of the instant

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application are drawn to methods for detecting the presence of a target nucleic acid molecule by detecting the cleavage of an invasive cleavage structure. The cleavage of the invasive cleavage structure is detected by detecting non-target cleavage products so that the instant patents and the instant application are claiming the same thing. For example claim 6 of the instant invention states "wherein said cleaving generates a non-target cleavage product" and claim 7 states "wherein said detecting the cleavage of said invasive cleavage structure comprises detecting said non-target cleavage product".

U.S. Patent No. 6,458,535 is drawn to a method of detecting the cleavage of nucleic acid using essentially the same steps as the instant application. The "cleavage structure" that is detected in claim 1(d) of the instant patent is the invasive cleavage structure of the instant application.

The disclosure is objected to because of the following informalities:

Applicants list 9 applications in the oath filed 1/15/02 as being priority documents for this application. The computer system of the USPTO lists 10 documents. Apparently the additional application listed (08/381,212) is a mistake and should be 09/381,212, which is also listed. However applicants list 07/756,386 which correspond to D337,472, a design patent having nothing to do with the subject matter of the instant application. Perhaps the correct application number should be 08/756,386. All of the applications are listed as continuations in part. Because of scanning of the application into IFW and because of the inordinate size of the instant application file, paper may have been omitted. Applicants are required to check the instant information and correct it appropriately. The first paragraph of the specification should be amended as appropriate since it does not agree with the oath.

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On pages 58 and 59, apparently "Figure 22" and "Figure 24" should be "Figure 22 A and B" and "Figure 24 A and B", respectively.

Appropriate correction is required.

Claim 38 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is indefinite in the recitation of "said non-target cleavage product", which term has no antecedent basis.

Claim 45 is indefinite in the recitation of "said first oligonucleotide ...said second oligonucleotide". There is no antecedent basis for these terms.

The Xu, et al. reference crossed through in the enclosed PTO-1449 may be present but the reference submitted has no journal name, volume, or page numbers, so that the examiner is unable to ascertain what the reference is. The other references crossed through were not present.

The examiner has been unable to find any reference that would anticipate or make obvious the claimed invention.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-

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0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
September 17, 2004